. AVIGEN. 003C1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

COUTO et al.

Serial No.:

09/740,211

Filing Date:

December 18, 2000

Title:

ADENO-ASSOCIATED VECTOR

COMPOSITIONS FOR EXPRESSION OF

Group

Art Unit:

1633

FACTOR VIII

Examiner:

Brian Whiteman

## PETITION TO MAKE SPECIAL UNDER MPEP 708.02, XII (SPECIAL STATUS FOR APPLICATION RELATING TO BIOTECHNOLOGY FILED BY APPLICANTS WHO ARE SMALL ENTITIES)

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

- I am Vice President for Business Development and Intellectual Property of AVIGEN, Inc. On behalf of AVIGEN, I hereby request that special status be granted to the above-reference application. This request fully complies with the requirements of M.P.E.P. 708.02(XII).
- The status of AVIGEN, Inc. as a small entity has already been established.

  The Verified Statement establishing small entity has been previously submitted.
- The patent application entitled "Adeno-Associated Vector Compositions for Expression of Factor VIII" encompasses rAAV-Factor VIII technology used in one of Avigen's leading research and development programs for the treatment of Hemophilia A. Avigen considers the invention to be a major asset of the company and it has invested significant time and effort in developing the technology. Thus, the subject matter of the application at issue is a major asset to AVIGEN, Inc.

I believe the development of a treatment for Hemophilia A using such rAAV-Factor VIII gene therapy technology, and the ability to raise money for the necessary clinical trials will be significantly impaired if the examination of the above-identified patent application is delayed.

Research in this area is expensive and funding difficult to obtain. Indeed, the ability to raise money to fund research is often (albeit, unfortunately) predicated on the speedy examination and issuance of a U.S. Patent.

Accordingly, if examination is delayed the development of this promising new technology will be significantly impaired.

Dated: 10-26-01

Kenneth G. Chahine,

V.P., Business Development and Intellectual Property